Ameliorating Active Ulcerative Colitis via an Orally Available Toll-Like Receptor-9 Modifier: A Prospective Open-Label, Multicenter Phase II Trial

By soreq

Abstract:

BACKGROUND: Treatment of active ulcerative colitis is associated with incomplete efficacy, adverse events, and loss of response. Toll-like receptor-9 mediates innate and adaptive immune response toward intestinal microorganisms. The oral synthetic oligonucleotide toll-like receptor-9 modulator has demonstrated anti-inflammatory properties in colitis murine models and a satisfactory safety profile in humans. AIM: To evaluate the efficacy and safety of BL-7040 (a Toll-like receptor-9 modulator) in patients with moderately active ulcerative colitis. METHODS: Moderately active ulcerative colitis patients were included in this multicenter, open-label phase IIa trial. Concomitant mesalamine and steroids at a stable dose were allowed. Clinical outcome was evaluated using the Mayo score, histology, and mucosal cytokine levels. Side effects were registered. RESULTS: Sixteen out of 22 patients completed a 5-week treatment course and 2-week follow-up. Six patients discontinued the study, three of them due to adverse events. Clinical remission was observed in two patients (12.5 %), and clinical response as well as mucosal healing were achieved in half (50 %) of the patients, while all others remained stable. Furthermore, mucosal neutrophil (p = 0.002) and mucosal interleukin-6 levels (p = 0.046) were significantly reduced in responders compared to non-responders. Toll-like receptor-9 was well tolerated with only one unrelated to study drug serious adverse event (hemoglobin decrease) and 29 mild-to-moderate adverse events. CONCLUSIONS: Oral administration of the Toll-like receptor-9 agonist BL-7040 appeared efficacious, safe and well tolerated in patients with moderately active ulcerative colitis.
UPCOMING EVENTS

Learn more about our exciting upcoming events!

read more

Studying at ELSC

Our Int'l Ph.D. program provides outstanding students with top-notch courses in computational neuroscience.

read more

The Building

The Jerusalem Brain Sciences Building will provide a state-of-the-art research and teaching facility for the Edmond and Lily Safra Center for Brain Sciences.

read more

ELSC Media Channel

Get into our media channel and investigate ELSC's latest videos: seminars, public lectures, courses and video articles.

read more

Source URL: https://elsc.huji.ac.il/soreq/publications/ameliorating-active-ulcerative-colitis-orally-available-toll-receptor-9-modifier-